

ADOPTED

BOARD OF SUPERVISORS COUNTY OF LOS ANGELES

#16 OCTOBER 12, 2010

achi a. Hamai

SACHLA, HAMAL

EXECUTIVE OFFICER

Los Angeles County Board of Supervisors

> Gloria Molina First District

October 05, 2010

Mark Ridlev-Thomas Second District

> Zev Yaroslavsky Third District

> > Don Knabe Fourth District

Michael D. Antonovich Fifth District October 03, 2010

The Honorable Board of Supervisors County of Los Angeles 383 Kenneth Hahn Hall of Administration 500 West Temple Street Los Angeles, California 90012

Dear Supervisors:

John F. Schunhoff, Ph.D. Interim Director

Gail V. Anderson, Jr., M.D. Interim Chief Medical Officer

313 N. Figueroa Street, Suite 912 Los Angeles, CA 90012

> Tel: (213) 240-8101 Fax: (213) 481-0503

APPROVAL OF AMENDMENT TO CANCER RESEARCH AND CARE SERVICES AGREEMENT WITH THE UNIVERSITY OF SOUTHERN CALIFORNIA KECK SCHOOL OF MEDICINE (SUPERVISORIAL DISTRICT 1)

3 VOTES

www.dhs.lacounty.gov

SUBJECT

To improve health

through leadership.

unough leadership,

service and education.

www.dhs.lacounty.gov

Request approval of an Amendment to extend the term of the Agreement to provide for the identification, selection, and participation of LAC+USC Medical Center patients in cancer research clinical trials.

IT IS RECOMMENDED THAT YOUR BOARD:



Authorize the Interim Director of Health Services (Interim Director), or his designee, to execute Amendment No. 1 to Agreement No. H-701062, with the University of Southern California (USC) Keck School of Medicine, effective upon Board approval to extend the term of the Agreement for the period of November 1, 2010 through October 31, 2011 for the continued provision of cancer research, care, treatment, and related services to LAC+USC Medical Center (LAC+USC) patients, 100 percent offset by the remaining unexpended funds in the Los Angeles Donation Fund Trust Account, (i.e., Sommer Cancer Research and Care Trust Fund).

The Honorable Board of Supervisors 10/5/2010 Page 2

PURPOSE/JUSTIFICATION OF RECOMMENDED ACTION

Approval of the recommended extension will allow the Interim Director to execute an Amendment, substantially similar to Exhibit I, with the USC Keck School of Medicine, to extend the agreement for one year to be able to utilize the remaining funds in the trust account for the continued provision of cancer research, care, treatment and related services for cancer patients at LAC+USC. The Agreement, approved by your Board on May 17, 2005, was established as a result of a bequest by the late Paul N. Sommer. The Sommer Cancer Research and Care Trust Fund did not specify a term to conclude the cancer research. The parties agreed to a "term" provision that specified Agreement would automatically be renewed through October 31, 2010 or until such time as any remaining funds and interest in the trust account are completely expended, or whichever of these two events sooner occurs.

Both parties agree that an extension is needed since there will be funds remaining as of October 31, 2010. Although the USC Keck School of Medicine intended to utilize all the funds, due to a shortage of nursing staff to provide screening services in some of the clinics, they were unable to fully expend the funds.

<u>Implementation of Strategic Plan Goals</u>

The recommended action supports Goal 4, Health and Mental Health, of the County's Strategic Plan.

FISCAL IMPACT/FINANCING

By November 1, 2010, approximately \$422,000 will remain in the trust account. Invoicing and payment are done on a quarterly basis. The remaining funds will be used for services during the extension period.

The Department of Health Services will continue to provide in-kind services to the USC Keck School of Medicine (e.g., use of County space, utilities, housekeeping services, phone services, etc.) to facilitate the provision of clinical services to LAC+USC patients.

FACTS AND PROVISIONS/LEGAL REQUIREMENTS

On May 17, 2005, your Board approved an Agreement between LAC+USC and the USC Keck School of Medicine to provide for the identification, selection, and participation of LAC+USC MC patients in cancer research clinical trials through April 30, 2010, at an approximate total cost of \$1.76 million with provisions to extend the term of the Agreement on a month-to-month basis until the remaining funds and interest in the trust account are completely expended, or until October 31, 2010, whichever of the two sooner occurs.

Contractor's services benefit and support cancer research and care by screening patients in the following LAC+USC clinics: Hematology, Gynecologic Oncology and Medical Oncology. Patients in these clinics are informed about available clinical trials that may be the best or only standard of care for their diseases such as newly diagnosed metastatic disease that include melanoma, pancreatic cancer and gastric cancer.

The Agreement has been updated with all the latest Board-mandated provisions. The Agreement may be terminated by either party upon 30 days' prior written notice. County Counsel has

The Honorable Board of Supervisors 10/5/2010 Page 3

approved Exhibit I as to form.

CONTRACTING PROCESS

Not applicable.

IMPACT ON CURRENT SERVICES (OR PROJECTS)

Approval of the recommendation will ensure the continued availability of cancer clinical trials to LAC +USC patients.

Respectfully submitted,



JOHN F. SCHUNHOFF, Ph.D. Interim Director

JFS:gh

Enclosures

c: Chief Executive Office County Counsel Executive Office, Board of Supervisors

CANCER RESEARCH AND CARE SERVICES AGREEMENT H-701062

USC KECK SCHOOL OF MEDICINE

PROJECTED AGREEMENT COSTS

NOVEMBER 1, 2010 THROUGH OCTOBER 31, 2011

Personnel, Salaries and Fringe Benefits

(3) Nurse Coordinators (i.e., 3 Full Time Equivalent [FTE] positions@\$75,000 per year with 34% [\$25,500] fringe benefits each).		\$3	01,500
(1) Tissue Acquisition (i.e., 1 FTE position @ \$30,000 per year with 34% [\$10,200 fringe benefits each).	Sub-total		<u>40,200</u> 41,700
Other Purchase of equipment (53-10" televisions), and	nd installation ¹	\$	80,000
		\$	80,000

Grand Total

\$421,700

¹ TVs will be utilized for the educational and interpretation services to LAC+USC cancer patients.

Contract No. H-701062

CANCER RESEARCH AND CARE SERVICES AGREEMENT

AMENDMENT NO. 1

THIS AMENDMENT is ma	ade and entered into this day of
, 2010,	
by and between	COUNTY OF LOS ANGELES (hereinafter "County"),
and	U.S.C. KECK SCHOOL OF MEDICINE (hereafter "Contractor").

WHEREAS, reference is made to that certain document entitled "CANCER RESEARCH AND CARE SERVICES AGREEMENT, dated May 17, 2005, and further identified as County Agreement No. H-701062 (hereafter referred to as "Agreement"; and

WHEREAS, Agreement is slated to expire on October 31, 2010; and

WHEREAS, it is the intent of the parties hereto to amend Agreement to extend its term for one year, and make the changes described hereinafter.

WHEREAS, said Agreement provides that changes may be made in the form of a written amendment which is formally approved and executed by both parties; and

NOW, THEREFORE, the parties hereby agree as follows:

1. This Amendment shall be effective upon Board approval.

- 2. Paragraph 1, "<u>TERM</u>", shall be deleted in its entirety and replaced with the following:
 - "1. <u>TERM</u>: The term of this Agreement shall commence on May 17, 2005 and shall continue, unless sooner terminated or canceled, in full force and effect to and including October 31, 2011.

This Agreement may be cancelled or terminated at any time, for any reason, with or without cause, by either party upon giving of at least thirty (30) calendar days prior written notice to the other.

Notwithstanding any other provision of this Paragraph, the failure of Contractor or its officers, employees, agents, or subcontractors, to comply with any of the terms of this Agreement or any written directions by or on behalf of County issued pursuant hereto shall constitute a material breach hereto, and this Agreement may be terminated by County immediately. County's failure to exercise this right of termination shall not constitute a waiver of such right, which may be exercised at any subsequent time."

3. Subparagraphs A and B of Paragraph 3, "BILLING AND PAYMENT", shall be deleted in their entirety and replaced with the following:

"3. BILLING and PAYMENT:

A. County agrees to compensate Contractor in accordance with the payment structure set forth in Exhibit A and Attachment A, revised as attached hereto and incorporated herein by reference.

- B. Contractor shall bill County quarterly in arrears in accordance with the terms, conditions, and rates set forth herein. All billings shall clearly reflect and provide reasonable detail of the services provided including, but not limited to, name and discipline (e.g. Nurse Coordinator and/or Tissue Acquisition Technician) of the person providing services, dates(s), and if needed, hours worked, hourly rate, and any other charges as set forth in this Agreement.

 Billings shall be prepared and forwarded to the: LAC+USC Healthcare Network Contract Invoices; P.O. Box 861749, Los Angeles, California, 90086, Attention: Contract Invoice Processing, on a monthly basis."
- 4. Paragraph 15, "CONTRACTOR'S OFFICE", shall be deleted in its entirety and replaced with the following:
 - "15. CONTRACTOR'S OFFICE: Contractor's primary business office is located at U.S.C. Keck School of Medicine, Health Sciences Campus, 2020 Zonal Avenue, #3451, Los Angeles, California 90033. Contractor's primary business telephone number is (323) 865-3920, facsimile/Fax number is (323) 865-0116, and e-mail address is dmoody@usc.edu. Contractor shall notify County, in writing, of any changes made to Contractor's primary business address, business telephone number, facsimile/Fax number, and/or e-mail address used in the provision of services herein, at least ten (10) calendar days prior to the effective date(s) thereof."
 - 5. Paragraph 16, "NOTICES", paragraph B", shall be replaced with the following:
 - "B. (1) U.S.C. Department of Contracts & Grants, 2250 Alcazar Street, CSC-219 Los Angeles, California 90033

Attention: Terry Hansen

Sr. Contract Administrator

(2) U.S.C. Keck School of Medicine Health Sciences Campus 2020 Zonal Avenue, #3451 Los Angeles, California 90033 Attention: Dianne Moody

Clinical Administrator"

- 6. Paragraph 14, "CONTRACTOR'S OBLIGATIONS AS A BUSINESS

 ASSOCIATE UNDER THE HEALTH INSURANCE PORTABILITY AND

 ACCOUNTABILITY ACT OF 1996 ("HIPPA")", of the Additional Provisions, shall be deleted in its entirety and replaced with the following:
- "14. CONTRACTOR'S OBLIGATIONS AS A BUSINESS ASSOCIATE UNDER HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

 AND THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (HITECH); The County is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Under this Agreement, the Contractor receives, has access to and/or creates Protected Health Information as defined in Exhibit B in order to provide those services. The County and the Contractor therefore agree to the terms of Exhibit B, Contractor's Obligations As a "Business Associate" Under Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) (Business Associate Agreement)."
- 7. Paragraph 33, "<u>CONTRACTOR RESPONSIBILITY AND DEBARMENT</u>", of the Additional Provisions, shall be deleted in its entirety and replaced with the following:

"33. CONTRACTOR'S RESPONSIBILITY AND DEBARMENT:

- A. A responsible Contractor is a Contractor who has demonstrated the attribute of trustworthiness, as well as quality, fitness, capacity and experience to satisfactorily perform the Agreement. It is the County's policy to conduct business only with responsible Contractors.
- B. Contractor is hereby notified that, in accordance with Chapter 2.202 of the County Code, if County acquires information concerning the performance of the Contractor on this Agreement or other Agreements, which indicates that Contractor is not responsible, County may, in addition to other remedies provided in this Agreement, debar Contractor from bidding or proposing, or being awarded, and/or performing work on County agreements for a specified period of time, which generally will not exceed five (5) years, but may exceed five (5) years or be permanent if warranted by the circumstances, and terminate any or all existing agreements the Contractor may have with County.
- C. County may debar a Contractor if the Board of Supervisors finds, in its discretion, that Contractor has done any of the following: (1) violated a term of an agreement with the County or a nonprofit corporation created by the County, (2) committed any act or omission which negatively reflects on the Contractor's quality, fitness, or capacity to perform an agreement with the County or any other public entity, or a nonprofit corporation created by County, or engaged in a pattern or practice which negatively reflects on same, (3) committed an act or offense which indicates a lack of business integrity or business honesty, or (4) made or submitted a false claim against the County or any other public entity.

- D. If there is evidence that Contractor may be subject to debarment, the Department will notify the Contractor in writing of the evidence which is the basis for the proposed debarment and will advise the Contractor of the scheduled date for a debarment hearing before the Contractor Hearing Board.
- E. The Contractor Hearing Board will conduct a hearing where evidence on the proposed debarment is presented. The Contractor and/or the Contractor's representative shall be given an opportunity to submit evidence at the hearing. After the hearing, the Contractor Hearing Board shall prepare a tentative proposed decision, which shall contain a recommendation regarding whether the Contractor should be debarred, and, if so, the appropriate length of time of the debarment. The Contractor and the Department shall be provided an opportunity to object to the tentative proposed decision prior to its presentation to the Board of Supervisors.
- F. After consideration of any objections, or if no objections are submitted, a record of the hearing, the proposed decision, and any other recommendation of the Contractor Hearing Board shall be presented to the Board of Supervisors. The Board of Supervisors shall have the right to modify, deny, or adopt the proposed decision and recommendation of the Contractor Hearing Board.
- G. If a Contractor has been debarred for a period of longer than five (5) years, that Contractor may after the debarment has been in effect for at least five (5) years, submit a written request for review of the debarment determination to reduce the period of debarment or terminate the debarment. The County may, in

its discretion, reduce the period of debarment or terminate the debarment if it finds that the Contractor has adequately demonstrated one or more of the following: (1) elimination of the grounds for which the debarment was imposed; (2) a bona fide change in ownership or management; (3) material evidence discovered after debarment was imposed; or (4) any other reason that is in the best interests of the County.

H. The Contractor Hearing Board will consider a request for review of a debarment determination only where (1) the Contractor has been debarred for a period longer than five (5) years; (2) the debarment has been in effect for at least five (5) years; and (3) the request is in writing, states one or more of the grounds for reduction of the debarment period or termination of the debarment, and includes supporting documentation. Upon receiving an appropriate request, the Contractor Hearing Board will provide notice of the hearing on the request. At the hearing, the Contractor Hearing Board shall conduct a hearing where evidence on the proposed reduction of debarment period or termination of debarment is presented. The hearing shall be conducted and the request for review decided by the Contractor Hearing Board pursuant to the same procedures as for a debarment hearing.

The Contractor Hearing Board's proposed decision shall contain a recommendation on the request to reduce the period of debarment or terminate the debarment. The Contractor Hearing Board shall present its proposed decision and recommendation to the Board of Supervisors. The Board of

Supervisors shall have the right to modify, deny, or adopt the proposed decision and recommendation of the Contractor Hearing Board.

- I. These terms shall apply to Subcontractors of County Contractors."
- 8. Paragraphs 38, "CONTRACTOR'S WARRANTY OF COMPLIANCE WITH

 COUNTY'S DEFAULTED PROPERTY TAX PROGRAM", and 39, "TERMINATION FOR

 BREACH OF WARRANTY TO MAINTAIN COMPLIANCE WITH COUNTY'S

 DEFAULTED PROPERTY TAX REDUCTION PROGRAM", shall be added to the

 Additional Provisions as follows:
- "38. CONTRACTOR'S WARRANTY OF COMPLIANCE WITH COUNTY'S

 DEFAULTED PROPERTY TAX REDUCTION PROGRAM:
 - A. Contractor acknowledges that County has established a goal of ensuring that all individuals and businesses that benefit financially from County through contract are current in paying their property tax obligations (secured and unsecured roll) in order to mitigate the economic burden otherwise imposed upon County and its taxpayers.
 - B. Unless Contractor qualifies for an exemption or exclusion, Contractor warrants and certifies that to the best of its knowledge it is now in compliance, and during the term of the Agreement will maintain compliance with Los Angeles Code Chapter 2.206.
- 39. TERMINATION FOR BREACH OF WARRANTY TO MAINTAIN

 COMPLIANCE WITH COUNTY'S DEFAULTED PROPERTY TAX REDUCTION

 PROGRAM: Failure of Contractor to maintain compliance with the requirements set forth in the above paragraph, "County's Warranty of Compliance with County's

Defaulted Property Tax Reduction Program", shall constitute default under this Agreement. Without limiting the rights and remedies available to County under any other provision of this Agreement, failure of Contractor to cure such default within ten (10) days of notice shall be grounds upon which County may terminate this Agreement and/or pursue debarment of Contractor, pursuant to County Code Chapter 2.206."

9. Except for the changes set forth herein above, Agreement shall not be changed in any respect by this Amendment.

IN WITNESS WHEREOF, the Board of Supervisors of the County of Los Angeles has caused this Amendment to be subscribed by its Director of Health Services, and Contractor has caused this Amendment to be subscribed in its behalf by its duly authorized officer, the day, month, and year first above written.

COUNTY OF LOS ANGELES

By	
,	John F. Schunhoff, Ph.D.
	Interim Director of Health Services
	U.S.C. KECK SCHOOL OF MEDICINE
	Affiliate
	Ву
	Signature
	Print Name
	Title
	(AFFIX CORPORATE SEAL HERE)
	(ALLIA CONFORATE SEAL HERE)

APPROVED AS TO FORM: Andrea Sheridan Ordin County Counsel

AMEND:USC Keck School of Medicine _gh:08/26/10

Exhibit B

CONTRACTOR'S OBLIGATIONS AS A BUSINESS ASSOCIATE UNDER THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 AND THE HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH ACT (BUSINESS ASSOCIATE AGREEMENT)

Under this Agreement, Contractor ("Business Associate") provides services ("Services") to County ("Covered Entity") and Business Associate receives, has access to or creates Protected Health Information in order to provide those Services.

Covered Entity is subject to the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191 ("HIPAA"), and regulations promulgated thereunder, including the Standards for Privacy of Individually Identifiable Health Information ("Privacy Regulations") and the Health Insurance Reform: Security Standards ("the Security Regulations") at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164 (together, the "Privacy and Security Regulations"). The Privacy and Security Regulations require Covered Entity to enter into a contract with Business Associate ("Business Associate Agreement") in order to mandate certain protections for the privacy and security of Protected Health Information, and those Regulations prohibit the disclosure to or use of Protected Health Information by Business Associate if such a contract is not in place.

Further, pursuant to the Health Information Technology for Economic and Clinical Health Act, Public Law 111-005 ("HITECH Act"), effective February 17, 2010, certain provisions of the HIPAA Privacy and Security Regulations apply to Business Associates in the same manner as they apply to Covered Entity and such provisions must be incorporated into the Business Associate Agreement.

This Business Associate Agreement and the following provisions are intended to protect the privacy and provide for the security of Protected Health Information disclosed to or used by Business Associate in compliance with HIPAA's Privacy and Security Regulations and the HITECH Act, as they now exist or may hereafter be amended.

Therefore, the parties agree as follows:

DEFINITIONS

- 1.1 "Breach" has the same meaning as the term "breach" in 45 C.F.R. § 164.402.
- 1.2 "<u>Disclose</u>" and "<u>Disclosure</u>" mean, with respect to Protected Health Information, the release, transfer, provision of access to, or divulging in any other manner of Protected Health Information outside Business Associate's internal operations or to other than its employees.

Effective 02/17/2010 HOA.668507.2

- 1.3 "<u>Electronic Health Record</u>" has the same meaning as the term "electronic health record" in the HITECH Act, 42 U.S.C. section 17921. Electronic Health Record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized health care clinicians and staff.
- 1.4 "Electronic Media" has the same meaning as the term "electronic media" in 45 C.F.R. § 160.103. Electronic Media means (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

The term "Electronic Media" draws no distinction between internal and external data, at rest (that is, in storage) as well as during transmission.

- 1.5 "<u>Electronic Protected Health Information</u>" has the same meaning as the term "electronic protected health information" in 45 C.F.R. § 160.103. Electronic Protected Health Information means Protected Health Information that is (i) transmitted by electronic media; (ii) maintained in electronic media.
- 1.6 "Individual" means the person who is the subject of Protected Health Information and shall include a person who qualifies as a personal representative in accordance with 45 C.F.R. § 164.502(g).
- 1.7 "Minimum Necessary" refers to the minimum necessary standard in 45 C.F.R. § 162.502 (b) as in effect or as amended.
- 1.8 "Privacy Rule" means the Standards for Privacy of Individually Identifiable Health Information at 45 Code of Federal Regulations (C.F.R.) Parts 160 and 164, also referred to as the Privacy Regulations.
- 1.9 "Protected Health Information" has the same meaning as the term "protected health information" in 45 C.F.R. § 160.103, limited to the information created or received by Business Associate from or on behalf of Covered Entity. Protected Health Information includes information that (i) relates to the past, present or future physical or mental health or condition of an Individual; the provision of health care to an Individual, or the past, present or future payment for the provision of health care to an Individual; (ii) identifies the Individual (or for which there is a reasonable basis

for believing that the information can be used to identify the Individual); and (iii) is received by Business Associate from or on behalf of Covered Entity, or is created by Business Associate, or is made accessible to Business Associate by Covered Entity. "Protected Health Information" includes Electronic Health Information.

- 1.10 "Required By Law" means a mandate contained in law that compels an entity to make a Use or Disclosure of Protected Health Information and that is enforceable in a court of law. Required by law includes, but is not limited to, court orders and court-ordered warrants; subpoenas or summons issued by a court, grand jury, a governmental or tribal inspector general, or any administrative body authorized to require the production of information; a civil or an authorized investigative demand; Medicare conditions of participation with respect to health care providers participating in the program; and statutes or regulations that require the production of information, including statutes or regulations that require such information if payment is sought under a government program providing benefits.
- 1.11 "Security Incident" means the attempted or successful unauthorized access, Use, Disclosure, modification, or destruction of information in, or interference with system operations of, an Information System which contains Electronic Protected Health Information. However, Security Incident does not include attempts to access an Information System when those attempts are not reasonably considered by Business Associate to constitute an actual threat to the Information System.
- 1.12 "Security Rule" means the Security Standards for the Protection of Electronic Health Information also referred to as the Security Regulations at 45 Code of Federal Regulations (C.F.R.) Part 160 and 164.
- 1.13 "Services" has the same meaning as in the body of this Agreement.
- 1.14 "<u>Unsecured Protected Health Information</u>" has the same meaning as the term "unsecured protected health information" in 45 C.F.R. § 164.402.
- 1.15 "<u>Use</u>" or "<u>Uses</u>" mean, with respect to Protected Health Information, the sharing, employment, application, utilization, examination or analysis of such Information within Business Associate's internal operations.
- 1.16 Terms used, but not otherwise defined in this Business Associate Agreement shall have the same meaning as those terms in the HIPAA Regulations and HITECH Act.

OBLIGATIONS OF BUSINESS ASSOCIATE

2.1 <u>Permitted Uses and Disclosures of Protected Health Information</u>. Business Associate:

- (a) shall Use and Disclose Protected Health Information only as necessary to perform the Services, and as provided in Sections 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 4.3 and 5.2 of this Agreement;
- (b) shall Disclose Protected Health Information to Covered Entity upon request;
- (c) may, as necessary for the proper management and administration of its business or to carry out its legal responsibilities:
 - (i) Use Protected Health Information; and
 - (ii) Disclose Protected Health Information if the Disclosure is Required by Law.

Business Associate shall not Use or Disclose Protected Health Information for any other purpose or in any manner that would constitute a violation of the Privacy Regulations or the HITECH Act if so Used or Disclosed by Covered Entity.

- 2.2 <u>Prohibited Uses and Disclosures of Protected Health Information</u>. Business Associate:
 - (a) shall not Use or Disclose Protected Health Information for fundraising or marketing purposes.
 - (b) shall not disclose Protected Health Information to a health plan for payment or health care operations purposes if the Individual has requested this special restriction and has paid out of pocket in full for the health care item or service to which the Protected Health Information solely relates.
 - (c) shall not directly or indirectly receive payment in exchange for Protected Health Information, except with the prior written consent of Covered Entity and as permitted by the HITECH Act. This prohibition shall not effect payment by Covered Entity to Business Associate. Covered Entity shall not provide such written consent except upon express approval of the departmental privacy officer and only to the extent permitted by law, including HIPAA and the HITECH Act.
- 2.3 Adequate Safeguards for Protected Health Information. Business Associate:
 - (a) shall implement and maintain appropriate safeguards to prevent the Use or Disclosure of Protected Health Information in any manner other than as permitted by this Business Associate Agreement. Business Associate agrees to limit the Use and Disclosure of Protected Health Information to the Minimum Necessary in accordance with the Privacy Regulation's minimum necessary standard as in effect or as amended.

(b) as to Electronic Protected Health Information, shall implement and maintain administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of Electronic Protected Health Information; effective February 17, 2010, said safeguards shall be in accordance with 45 C.F.R. Sections 164.308, 164.310, and 164.312, and shall comply with the Security Rule's policies and procedure and documentation requirements.

2.4 Reporting Non-Permitted Use or Disclosure and Security Incidents and Breaches of Unsecured Protected Health Information. Business Associate

- (a) shall report to Covered Entity each Use or Disclosure of Protected Health Information that is made by Business Associate, its employees, representatives, Agents, subcontractors, or other parties under Business Associate's control with access to Protected Health Information but which is not specifically permitted by this Business Associate Agreement or otherwise required by law.
- (b) shall report to Covered Entity each Security Incident of which Business Associate becomes aware.
- (c) shall notify Covered Entity of each Breach by Business Associate, its employees, representatives, agents or subcontractors of Unsecured Protected Health Information that is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate. Business Associate shall be deemed to have knowledge of a Breach of Unsecured Protected Health Information if the Breach is known, or by exercising reasonable diligence would have been known, to any person, other than the person committing the Breach, who is an employee, officer, or other agent of the Business Associate as determined in accordance with the federal common law of agency.
- 2.4.1 <u>Immediate Telephonic Report.</u> Except as provided in Section 2.4.3, notification shall be made immediately upon discovery of the non-permitted Use or Disclosure of Protected Health Information, Security Incident or Breach of Unsecured Protected Health Information by telephone call to (562) 940-3335.
- 2.4.2 <u>Written Report</u>. Except as provided in Section 2.4.3, the initial telephonic notification shall be followed by written notification made without unreasonable delay and in no event later than three (3) business days from the date of discovery of the non-permitted Use or Disclosure of Protected Health Information, Security Incident, or Breach by the Business Associate to the Chief Privacy Officer at:

Chief Privacy Officer
Kenneth Hahn Hall of Administration

500 West Temple Street Suite 525 Los Angeles, California 90012 HIPAA@auditor.lacounty.gov (213) 974-2166

- (a) The notification required by section 2.4 shall include, to the extent possible, the identification of each Individual whose Unsecured Protected Health Information has been, or is reasonably believed by the Business Associate to have been, accessed, acquired, Used, or Disclosed; and
- (b) the notification required by section 2.4 shall include, to the extent possible, all information required to provide notification to the Individual under 45 C.F.R. 164.404(c), including:
 - (i) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - (ii) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
 - (iii) Any other details necessary to conduct an assessment of whether there is a risk of harm to the Individual:
 - (iv) Any steps Business Associate believes that the Individual could take to protect him or herself from potential harm resulting from the breach:
 - (v) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to the Individual, and to protect against any further Breaches; and
 - (vi) The name and contact information for the person most knowledgeable regarding the facts and circumstances of the Breach.

If Business Associate is not able to provide the information specified in section 2.3.2 (a) or (b) at the time of the notification required by section 2.4.2, Business Associate shall provide such information promptly thereafter as such information becomes available.

2.4.3 Request for Delay by Law Enforcement. Business Associate may delay the notification required by section 2.4 if a law enforcement official states to

Business Associate that notification would impede a criminal investigation or cause damage to national security. If the law enforcement official's statement is in writing and specifies the time for which a delay is required, Business Associate shall delay notification, notice, or posting for the time period specified by the official; if the statement is made orally, Business Associate shall document the statement, including the identity of the official making the statement, and delay the notification, notice, or posting temporarily and no longer than 30 days from the date of the oral statement, unless a written statement as described in paragraph (a) of this section is submitted during that time.

- 2.5 <u>Mitigation of Harmful Effect</u>. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a Use or Disclosure of Protected Health Information by Business Associate in violation of the requirements of this Business Associate Agreement.
- 2.6 <u>Breach Notification</u>. Business Associate shall, to the extent Covered Entity determines that there has been a Breach of Unsecured Protected Health Information, provide Breach notification for each and every Breach of Unsecured Protected Health Information by Business Associate, its employees, representatives, agents or subcontractors, in a manner that permits Covered Entity to comply with its obligations under Subpart D, Notification in the Case of Breach of Unsecured PHI, of the Privacy and Security Regulations, including:
 - (a) Notifying each Individual whose Unsecured Protected Health Information has been, or is reasonably believed to have been, accessed, acquired, Used, or Disclosed as a result of such Breach:
 - (b) The notification required by paragraph (a) of this Section 2.6 shall include, to the extent possible:
 - (i) A brief description of what happened, including the date of the Breach and the date of the discovery of the Breach, if known;
 - (ii) A description of the types of Unsecured Protected Health Information that were involved in the Breach (such as whether full name, social security number, date of birth, home address, account number, diagnosis, disability code, or other types of information were involved);
 - (iii) Any steps the Individual should take to protect him or herself from potential harm resulting from the Breach;
 - (iv) A brief description of what Business Associate is doing to investigate the Breach, to mitigate harm to individuals, and to protect against any further Breaches; and

- (v) Contact procedures for Individual(s) to ask questions or learn additional information, which shall include a toll-free telephone number, an e-mail address, Web site, or postal address.
- (vi) The notification required by paragraph (a) of this section shall be written in plain language.

Covered Entity, in its sole discretion, may elect to provide the notification required by this Section 2.6, and Business Associate shall reimburse Covered Entity any and all costs incurred by Covered Entity, including costs of notification, internet posting, or media publication, as a result of Business Associate's Breach of Unsecured Protected Health Information.

- 2.7 Availability of Internal Practices, Books and Records to Government Agencies. Business Associate agrees to make its internal practices, books and records relating to the Use and Disclosure of Protected Health Information available to the Secretary of the federal Department of Health and Human Services for purposes of determining Covered Entity's compliance with the Privacy and Security Regulations. Business Associate shall immediately notify Covered Entity of any requests made by the Secretary and provide Covered Entity with copies of any documents produced in response to such request.
- 2.8 Access to Protected Health Information. Business Associate shall, to the extent Covered Entity determines that any Protected Health Information constitutes a "designated record set" as defined by 45 C.F.R. § 164.501, make the Protected Health Information specified by Covered Entity available to the Individual(s) identified by Covered Entity as being entitled to access and copy that Protected Health Information. Business Associate shall provide such access for inspection of that Protected Health Information within two (2) business days after receipt of request from Covered Entity. Business Associate shall provide copies of that Protected Health Information within five (5) business days after receipt of request from Covered Entity. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act.
- 2.9 Amendment of Protected Health Information. Business Associate shall, to the extent Covered Entity determines that any Protected Health Information constitutes a "designated record set" as defined by 45 C.F.R. § 164.501, make any amendments to Protected Health Information that are requested by Covered Entity. Business Associate shall make such amendment within ten (10) business days after receipt of request from Covered Entity in order for Covered Entity to meet the requirements under 45 C.F.R. § 164.526.
- 2.10 <u>Accounting of Disclosures</u>. Upon Covered Entity's request, Business Associate shall provide to Covered Entity an accounting of each Disclosure of Protected Health

Information made by Business Associate or its employees, agents, representatives or subcontractors, in order to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528 and/or the HITECH Act which requires an Accounting of Disclosures of Protected Health Information maintained in an Electronic Health Record for treatment, payment, and health care operations.

Any accounting provided by Business Associate under this Section 2.10 shall include: (a) the date of the Disclosure; (b) the name, and address if known, of the entity or person who received the Protected Health Information; (c) a brief description of the Protected Health Information disclosed; and (d) a brief statement of the purpose of the Disclosure. For each Disclosure that could require an accounting under this Section 2.10, Business Associate shall document the information specified in (a) through (d), above, and shall securely maintain the information for six (6) years from the date of the Disclosure. Business Associate shall provide to Covered Entity, within ten (10) business days after receipt of request from Covered Entity, information collected in accordance with this Section 2.10 to permit Covered Entity to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 C.F.R. § 164.528. If Business Associate maintains an Electronic Health Record, Business Associate shall provide such information in electronic format to enable Covered Entity to fulfill its obligations under the HITECH Act.

2.11 <u>Indemnification</u>. Business Associate shall indemnify, defend, and hold harmless Covered Entity, including its elected and appointed officers, employees, and agents, from and against any and all liability, including but not limited to demands, claims, actions, fees, costs, penalties and fines (including regulatory penalties and/or fines), and expenses (including attorney and expert witness fees), arising from or connected with Business Associate's acts and/or omissions arising from and/or relating to this Business Associate Agreement; Business Associate's obligations under this provision extend to compliance and/or enforcement actions and/or activities, whether formal or informal, of Secretary of the federal Department of Health and Human Services and/or Office for Civil Rights.

OBLIGATION OF COVERED ENTITY

3.1 <u>Obligation of Covered Entity</u>. Covered Entity shall notify Business Associate of any current or future restrictions or limitations on the use of Protected Health Information that would affect Business Associate's performance of the Services, and Business Associate shall thereafter restrict or limit its own uses and disclosures accordingly.

TERM AND TERMINATION

- 4.1 <u>Term.</u> The term of this Business Associate Agreement shall be the same as the term of this Agreement. Business Associate's obligations under Sections 2.1 (as modified by Section 4.2), 2.4, 2.5, 2.6, 2.7, 2.8, 2.9, 2.10, 4.3 and 5.2 shall survive the termination or expiration of this Agreement.
- 4.2 <u>Termination for Cause</u>. In addition to and notwithstanding the termination provisions set forth in this Agreement, upon either party's knowledge of a material breach by the other party, the party with knowledge of the other party's breach shall:
 - (a) Provide an opportunity for the breaching party to cure the breach or end the violation and terminate this Agreement if the breaching party does not cure the breach or end the violation within the time specified by the non-breaching party;
 - (b) Immediately terminate this Agreement if a party has breached a material term of this Agreement and cure is not possible; or
 - (c) If neither termination nor cure is feasible, report the violation to the Secretary of the federal Department of Health and Human Services.
- 4.3 <u>Disposition of Protected Health Information Upon Termination or Expiration.</u>
 - (a) Except as provided in paragraph (b) of this section, upon termination for any reason or expiration of this Agreement, Business Associate shall return or destroy all Protected Health Information received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no copies of the Protected Health Information.
 - (b) In the event that Business Associate determines that returning or destroying the Protected Health Information is infeasible, Business Associate shall provide to Covered Entity notification of the conditions that make infeasible. If return or destruction is infeasible, Business Associate shall extend the protections of this Business Associate Agreement to such Protected Health Information and limit further Uses and Disclosures of such Protected Health Information to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such Protected Health Information.

MISCELLANEOUS

5.1 <u>No Third Party Beneficiaries</u>. Nothing in this Business Associate Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

- 5.2 <u>Use of Subcontractors and Agents</u>. Business Associate shall require each of its agents and subcontractors that receive Protected Health Information from Business Associate, or create Protected Health Information for Business Associate, on behalf of Covered Entity, to execute a written agreement obligating the agent or subcontractor to comply with all the terms of this Business Associate Agreement.
- 5.3 <u>Relationship to Services Agreement Provisions</u>. In the event that a provision of this Business Associate Agreement is contrary to another provision of this Agreement, the provision of this Business Associate Agreement shall control. Otherwise, this Business Associate Agreement shall be construed under, and in accordance with, the terms of this Agreement.
- 5.4 <u>Regulatory References</u>. A reference in this Business Associate Agreement to a section in the Privacy and/or Security Regulations means the section as in effect or as amended.
- 5.5 <u>Interpretation</u>. Any ambiguity in this Business Associate Agreement shall be resolved in favor of a meaning that permits Covered Entity to comply with the Privacy and Security Regulations.
- 5.6 <u>Amendment</u>. The parties agree to take such action as is necessary to amend this Business Associate Agreement from time to time as is necessary for Covered Entity to comply with the requirements of the Privacy and Security Regulations and other privacy laws governing Protected Health Information.